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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,827	04/13/2006	Victor de Lorenzo Prieto	020884.1	8039

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
07/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,827	DE LORENZO PRIETO ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,8,12,15,22,28,31,35,38-42,44,45,47,49 and 51-59* is/are pending in the application.

4a) Of the above claim(s) *38-42,44,45,49,56,58 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,8,12,15,22,28,31,35,47,51-55 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 5/26/2009 is acknowledged. The traversal is on the ground(s) that the European Patent Office did not find a lack of unity in the international search of the case. Applicant argues that the EPO concluded that the claims met the requirement for unity of invention since no objections on said requirement were issued.

This is not found persuasive because the fact that the EPO chose to search all of the claims does not imply that the claims have met the requirement for unity of invention. It simply means that the searcher chose, for whatever reason, to search all of the claims. Furthermore, the decisions made by the EPO in the PCT are not binding in the present case and applicant has shown no reason why the findings set forth in the restriction requirement are incorrect.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3-4, 8, 12, 15, 22, 28, 31, 35, 38-42, 44-45, 47, 49, and 51-59 are pending. Claims 38-42, 44-45, 49, 56, and 58-59 are withdrawn as being drawn to non-elected inventions. Claims 1, 3-4, 8, 12, 15, 22, 28, 31, 35, 47, 51-55, and 57 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 5/10/2006 has been considered. An initialed copy is enclosed.

Specification

The use of the trademark TWEEN has been noted in this application on page 26. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that the cited occurrence of improper use is only exemplary and applicant should review the specification to correct any other use of trademarks.

Claim Objections

Claim 54 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The parent claim (claim 53) is already a vector; therefore, claim 54, which refers to a vector comprising the DNA construct of claim 53, is not further limiting.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-4, 8, 12, 15, 22, 28, 31, 35, 47, 51-55, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fernandez *et al.* (Appl. Environ. Microbiol., 66:5024-5029, 2000; IDS filed 5/10/2006) in view of Pack *et al.* (Biochem., 31:1579-1584, 1992; IDS filed 5/10/2006).

The instant claims are drawn to DNA constructs, vectors, and cells comprising said construct, where the construct comprises at least one first nucleic acid sequence coding for a product of interest, a second nucleic acid sequence coding for a dimerization domain, and a third nucleic acid sequence coding for *E. coli* HlyA.

Fernandez *et al.* disclose a DNA construct comprising an *E. coli* HlyA secretion protein fused to an scFv antibody. The vector containing the construct contains the scFv cloned in-frame with the 3' end of *E. coli hlyA*, in addition to a epitope tag and a histidine tag (page 5025, column 2, paragraphs 2 and 4). Said vector was placed into *E. coli* for expression (page 5026, column 2). With regard to claim 47, the intended use of the product is given no patentable weight.

Fernandez *et al.* differs from the instant invention in that the construct lacks a dimerization domain and a spacer between the scFV and the dimerization domain.

Pack *et al.* disclose miniantibodies, which are dimeric scFvs that contain a dimerization domain and a hinge peptide between the dimerization domain and the scFV fragment (see abstract and page 1580, column 2, paragraph 2). The addition of the dimerization domain (a leucine zipper) allows for the creation of bivalent fragments which have increased avidity (page 1579, column 2).

It would have been obvious to one of ordinary skill in the art, at the time of invention, to add a dimerization domain, as disclosed by Pack *et al.* to the scFv antibody/HlyA fusion of Fernandez *et al.*, because Pack *et al.* teach that the addition of a leucine zipper to dimerize the scFv antibodies allows for the creation of bivalent fragments which have increased avidity.

One would have had a reasonable expectation of success because the use of HlyA as a secretion mechanism was well known and had been used for many different proteins at the time of invention (including for expression of scFVs, as demonstrated by Fernandez *et al.*).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645